## **REMARKS**

The Office Action of July 12, 2005, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

In the above Office Action, claims 1, 2, 5, 6, 11-13, 15 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Faddis* (U.S. Patent No. 5,266,275) in view of *Spence* (U.S. Patent No. 4,919,888); claims 3, 4, 7-9 and 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable of *Faddis* in view of *Spence*, and further in view of *Quehl* (U.S. Patent No. 4,165,404); claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Faddis* in view of *Spence* (U.S. Patent No. 4,919,888) and *Quehl* and further in view of *Leimbacher et al.* (U.S. Patent No. 5,837,181); claims 14 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Faddis* in view of *Spence* and further in view of *Houston et al.* (U.S. Patent No. 5,894,014).

The Examiner's objections to the drawings are also noted, and submitted herewith is an amended Figure 1 illustrating the recited "inlet" integrally formed with the chamber as inlet 3d. The specification has also been amended to include the reference numeral 3d and to correct the inconsistent use of reference numeral 3c. With respect to the Examiner's contention that releasable fastening means must also be illustrated, Applicants respectfully disagree. The language in the claim does not positively recite "releasable fastening means" as the Examiner contends but rather, merely indicates that the sterilization chamber "is releasably fastened within the sterilization device." Accordingly, illustration of fastening means in the drawings should not be required.

As set forth above, amended claim 1 is directed to a sterilization chamber for use in a sterilization device. The sterilization chamber comprises a front portion including a front opening for allowing access to said chamber, a rear portion, and a chamber body portion disposed therebetween. The sterilization chamber is adapted to enclose goods to be sterilized during a sterilization process. As further recited, the sterilization chamber is releasably fastened within the sterilization device by releasably connecting the front portion and the rear portion to the housing of the sterilization device. The sterilization chamber comprises at least an inlet integrally formed with said chamber for releasable connection to a sterilant source from the sterilization device and an interior of said sterilization chamber is pressurized during the sterilization process so as to define a sealed pressure chamber. Further, the sterilization chamber comprises a self supported structure being essentially manufactured from a polymeric material.

The primary reference upon which the Examiner relies, *Faddis*, is directed to an ozone sterilization system comprising a primary chamber defining the sterilization chamber that is "maintained" during the sterilization cycle within a secondary safety containment chamber. The primary chamber is a rectangular pan 36 with an open top for covering by a lid 37. *Faddis* does not disclose a sterilization chamber comprising a front portion including a front opening for allowing access to said chamber, a rear portion, and a chamber body portion disposed therebetween, as now recited in claim 1. The Examiner relies upon the disclosure in *Faddis* of the sterilization chamber 35 being removable to meet the previously recited limitations of the sterilization chamber being releasably fastened within the sterilization device.

Applicants respectfully traverse this rejection and note that claim 1, as amended,

further defines releasable fastening as releasably connecting the front portion and the rear portion to the housing of the sterilization device. These fastenings are not disclosed or suggested in *Faddis* and in fact, *Faddis* teaches merely quick disconnect inlet and exhaust line couplings and the humidity probe or sensor and male couplings in order to remove the primary chamber 35 (col. 6, lines 46-50) -- not the unfastening of a releasable fastening as in the present invention.

The above-noted fastening differences are to be expected in that *Faddis* discloses a sterile container, not a sterilization chamber as in the present invention. Sterile containers are well-known in the art to the skilled person. A sterile container is a box for accommodating and storing in a sterile manner surgical instruments or material, wherein the box comprises an accommodating space formed by a container bottom and container walls, a lid for closing the accommodating space. Thus, surgical material or instruments, for example, are stored in such sterile containers in a sterile manner. As the lid and its sealing may be contaminated the whole container is placed in and sterilized in a sterilization chamber of a sterilizing apparatus.

Faddis relates to a sterilization system using ozone as a sterilization agent. The system comprises a primary chamber which is placed within a second separate outer chamber. As ozone is considered to be poisonous, even at low percentages, the second chamber is adapted to vent the ozone to a destruction chamber. The Examiner appears to rely upon the disclosure at col. 6, lines 46-55 to meet the claim limitation that "an interior of said sterilization chamber is pressurized during the sterilization process so as to define a sealed pressure chamber." Applicants note however that neither the primary nor the second chamber in Faddis is adapted to be

pressurized since the ozone used as the sterilzation agent is preferably "at or near atmospheric pressure and standard room temperature." See col. 5, lines 24-29; col. 7, lines 49-53. The temperature used in the sterilization process is low, room temperature or standard temperature and the highest indicated temperature is 31°C (see col. 7 line 61), thus emphasizing the significant differences in temperature when compared to steam sterilization as in the present invention. Applicants note that the presently pending claims do not specifically recite steam sterilization or pressurized as requiring pressure above atmospheric pressure; however, applicants would be willing to add these additional limitations in an effort to expedite the prosecution of the present application.

The Examiner relies upon the secondary referect to *Spence* for its disclosure of a chamber manufactured from a polymeric material. However, as pointed out above, *Faddis* does not disclose that an interior of the sterilization chamber is pressurized (above atmospheric pressure) during a sterilization process, and *Spence* also fails to teach this limitation. Accordingly, the substitution of the plastic box of *Spence* for the metal sterilization container in *Faddis* still does not render the claimed invention obvious, as neither box is adapted to be internally pressurized, i.e., "an interior of said sterilisation chamber is pressurized during the sterilization process", as recited in claim 1.

Accordingly, for at least the reasons set forth above, Applicants respectfully submit that the rejections of independent claim 1 have been obviated; the remaining claims being patentable based at least upon their dependence on claim 1.

In addition, claim 20 has been amended as set forth above to clarify that the chamber is provided with a pair of integrally formed tracks, in which the sealing

chamber door may be slidably mounted, and that when said releasably fastened

chamber is removed from the sterilization device said tracks are also removed

therewith. The reference to Houston upon which the Examiner relies for its teaching

of a door and tracks does not suggest that the tracks be formed with the chamber

nor that the tracks are removable when the chamber is removed. Rather, the door

structure in Houston is quite dependent upon the overall sterilization device and is

unlikely to be separable therefrom. Thus, claim 20 is patentable based as well upon

this further feature.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully submit

that the claims of the present application are now in condition for allowance, and an

early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the

Examiner believe that a telephone conference would be helpful in resolving any

remaining issues pertaining to this application; the Examiner is kindly invited to call

the undersigned counsel for Applicants regarding the same.

Respectfully submitted,

**BUCHANAN INGERSOLL PC** 

(INCLUDING ATTORNEYS FROM BURNS DOANE SWECKER & MATHIS)

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## **AMENDMENTS TO THE DRAWINGS:**

The attached sheet of drawings includes changes to Fig. 1. This sheet, which includes Fig. 1, replaces the original sheet including Fig. 1.

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

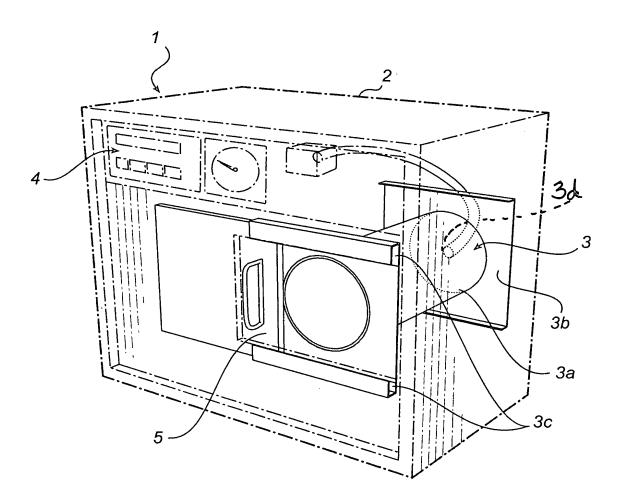


Fig. 1